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EXAMINER

HO, UYEN T

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/664,970

Applicant(s)

BETELIA ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 21-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-20, drawn to an apparatus for delivering a prostheses, classified in class 623, subclass 1.11.
 - II. Claims 21-36, drawn to a method of making a sheath for delivering a treatment, classified in class 623, subclass 1.11.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the apparatus of invention I can be made by a different process.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Mr. William English on 7/11/2002 a provisional election was made without traverse to prosecute the invention of I, claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-36 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The disclosure is objected to because of the following informalities: Page 22, lines 5-12, "Patent No. 5,443,400" does not disclosed "the stent 50" as applicants indicated.

Appropriate correction is required.

Claim Objections

7. Claim 1 is objected to because of the following informalities: In line 17, "the distal end" should be "the distal end of the bumper member" and in line 18, "a proximal end of the prosthesis" should be "the proximal end of the prosthesis." Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claim 1 recites the limitation "the sheath" in line 17. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiktor (4,681,110). Wiktor et al. disclose an apparatus including:

In regard to claims 1, 6 and 7,

- A delivery sheath (16) has a distal end including flexible leaflets (18) being separated by slits (19) and bias toward a closed position but being resiliently deflectable to an open position.
- A tubular prosthesis (22) is disposed within the lumen of the sheath.
- An elongate bumper (23) prevents axial displacement of the prosthesis.

In regard to claim 2,

- The prosthesis comprising a self expanding stent (col. 3, line 25 to col. 4, line 12)

In regard to claims 3-4,

- The leaflets define a substantially round bullet or conical shape in the closed position (figs. 1 and 5).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1, 3-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bramfitt et al. (5,935,135) in view of Martinez et al. (5,453,090). Bramfitt et al. disclose an apparatus including: an stent delivery sheath (10), a tubular prosthesis (30), an elongated bumper member (26) having an extension element (24), the extension element having a lumen for receiving a guidewire (fig. 1), radiopaque markers (41) on the distal end of the extension element (41) of the bumper member (26). However, Bramfitt et al. do not disclose the elongated delivering sheath having leaflets, as claimed. Martinez et al. disclose a stent delivery sheath including leaflets defining the shapes in a closed position, as claimed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the delivery sheath of Bramfitt et al. to have leaflets defining the shapes as disclosed by Martinez et al. in order to prevent injury to the wall of a vessel.

In regard to claim 7, it would have been obvious matter of design choice to modify the delivery sheath of Bramfitt et al. in view of Martinez et al., as described above to further have weakened regions between the leaflets and the regions being tearable upon retraction of the sheath, since applicant has not disclosed that having the weakened regions between the leaflets solves any stated problem or is for any

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particular purpose and it appears that the sheath would perform equally well with the leaflets having or not having the weakened regions between.

In regard to claims, 10 and 11-20, it would have been obvious matter of design choice to modify the apparatus of Bramitt et al. in view of Martinez et al. to have a bumper member comprising a helical coil, since applicant has not disclosed that having the bumper member comprising a helical coil solves any stated problem or is for any particular purpose and it appears that the apparatus would perform equally well with the bumper member having or not having a helical coil.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lau et al. (5,782,855), Querals et al. (5,290,295), Yurek et al. (5,662,703), Fitz (6,146,415), and Anderson et al. (5,800,517) disclose a prosthesis delivery apparatus having a delivery sheath similar to the delivery sheath of the present invention.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



(Jackie) Tan-Uyen T. Ho
July 12, 2002



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